

LEWIS & HARRISON

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May 15, 2012

Wanda Henson, Chemical Review Manager
Regulatory Management Branch
Antimicrobials Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yard
Arlington, VA 22202

re: Data Call-In for Zinc Borate
Registrant: U.S. Borax Inc.
Product: Borogard ZB, EPA Reg. No. 1624-120
Submission of Data Call-In Response and Requirements Status and
Registrant's Response Forms

Dear Ms. Henson:

On behalf of U.S. Borax Inc., I am responding to the Data Call-In issued by the Agency for the active ingredient, zinc borate. Please find enclosed the following completed forms:

- Data Call-In Response
- Requirements Status and Registrant's Response

In addition, there is an attachment to the Requirements Status and Registrant's Response form.

If you have any questions about this response, please contact me at (202) 393-3903, ext. 14 or e-mail me at eharrison@lewisharrison.com

Sincerely,



Eliot Harrison
Agent for U.S. Borax

United States Environmental Protection Agency
Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0174

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address U.S. BORAX INC. 12510 PROSPERITY DRIVE, SUITE 160 SILVER SPRING, MD 20904		2. Case # and Name N/A - Zinc borate (3ZnO, 2B03, 3.5H ₂ O; mw 434.66) Chemical # and Name: 128859 Zinc borate (3ZnO, 2B03, 3.5H ₂ O; mw 434.66)		3. Date and Type of DCI and Number 03-Feb-2012 GENERIC ID # GDCI-128859-1079	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."
1624-120			✓	N/A	N/A
8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <u>E. Smith, Agent for U.S. Borax</u>				9. Date 5/15/2012	
10. Name of Company U.S. Borax				11. Phone Number 202-393-3903	

2/14

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174


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4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Applicator Exposure Data Requirements (Conventional Chemical)								
875.1100	Dermal exposure--outdoor	N				X,BB	TEP	24	1,3
875.1200	Dermal exposure--indoor	N				X,BB	TEP	24	1,3
875.1300	Inhalation exposure--outdoor	N				X,BB	TEP	24	1,3
875.1400	Inhalation exposure--indoor	N				X,BB	TEP	24	1,3
875.1600	Application exposure monitoring data reporting (3)	N				X,BB	TEP	24	1,3
875.1700	Product Use Information	N				X,BB	TEP	24	1
875.2700	Product Use Information	N				X,BB	TEP	8	1
	Nontarget Plant Protection Data Requirements (Conventional Chemical)								
850.5400	Algal toxicity, Tiers 1 and II (2)	N				X,BB	TEP; TGA1	12	2
10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <u>Keith, Agent for U.S. Borax</u>							11. Date 5/15/2012		
12. Name of Company <u>U.S. Borax</u>							13. Phone Number (202) 393-3903 ext. 14		

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174

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			1	2	3				
875.2300	Indoor surface residue dissipation (1)	Y				X,BB	TEP	24	1, 3
875.2800	Description of human activity	N				X,BB	TEP	12	1
Toxicology Data Requirements (Conventional Chemical)									
870.1300	Acute inhalation toxicity	N				X,BB	EP; MP; TGAI	8	0
870.3465	90-day inhalation toxicity	N				X,BB	TGAI	24	2
835.3110	Ready biodegradability	N				X,BB		24	9
850.6800	Modified Activated Sludge Respiration Inhibition	N				X,BB		12	2
									

**ATTACHMENT TO REQUIREMENTS STATUS AND REGISTRANT'S
RESPONSE FORM**

Environmental Fate Data Requirements

Study Title: Ready Biodegradability
Guideline Number: 835.3110

U.S. Borax is requesting that the Agency reconfirm that this data requirement had previously been waived. In response to prior comments submitted by U.S. Borax, the Agency had previously determined that a Ready Biodegradability study was not necessary (see attached page).

Study Title: Modified Activated Sludge Respiration
Guideline Number: 850.6800

U.S. Borax has agreed to cost-share with Royce Associates the development of data that will satisfy this study requirement (see attached letters).

Toxicology Data Requirements

Study Title: Acute Inhalation Study
Guideline Number: 870.3100

U.S. Borax will submit an existing study to satisfy this data requirement.

Study Title: 90-day Inhalation Toxicity
Data Requirement: 870.3465

U.S. Borax has agreed to cost-share with Royce Associates the development of data that will satisfy this study requirement (see attached letters).

Non-Target Plant Protection Data Requirements

Study Title: Algal Toxicity, Tiers I and II
Data Requirement: 850.5400

U.S. Borax has agreed to cost-share with Royce Associates the development of data that will satisfy this study requirement (see attached letters).

Exposure (Applicator and Post-Applicator) Data Requirements

Study Title: Dermal Exposure -Outdoor
Guideline Number: 875.1100

Study Title: Dermal Exposure - Indoor
Guideline Number: 875.1200

Study Title: Inhalation Exposure -Outdoor
Guideline Number: 875.1100

Study Title: Inhalation Exposure - Indoor
Guideline Number: 875.1200

Study Title: Application Exposure Monitoring Data Reporting
Guideline Number: 875.1600

Study Title: Indoor Surface Residue Dissipation
Guideline Number: 875.2300

U.S. Borax will satisfy the above data requirements by either: 1) citing the exposure studies being conducted by the Antimicrobial Exposure Task Force II (AETFII); 2) by conducting new studies; 3) by cost-sharing in the development of the required exposure studies. U.S. Borax anticipates making final decision on which option is will select by July 15, 2012.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 13, 2008

MEMORANDUM

SUBJECT: Responses to U.S. Borax Inc's Ninety-Day Public Comments on Proposed Tier I Environmental Fate and Ecotoxicity Data Needs to Conduct an Environmental Fate and Ecological Risk Assessment for the Registration Review of Zinc Borate.

PC Code: 128859
CAS#: 12447-61-9

Case No.: 5025
DP Barcode: 341318

FROM: Srinivas Gowda, Microbiologist/Chemist *Srinivas Gowda*
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

TO: Mark Hartman, Branch Chief
Diane Isbell, Team Leader/Chemical Review Manager
Regulatory Management Branch II
Antimicrobials Division (7510P)

Timothy McMahon, Risk Assessor

THRU: Siroos Mostaghimi, Team Leader, Team one *Mark for*
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

Norman Cook, Branch Chief *Norman Cook*
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

Attached are responses to ninety-day public comments by U.S. Borax Inc., on anticipated environmental fate and ecological effects data needs in Zinc borate's Registration Review Summary Document.

still needed to assess the distribution of the antimicrobial among the solid and aqueous phases of WWTPs.

3. U.S. Borax's Comment:

Ready Biodegradability (OPPTS GLN 835.3110)

- The intent of this study is to determine the likelihood that an antimicrobial will biodegrade during the wastewater treatment process. However, zinc borate is an inorganic compound that is not subject to biodegradation or metabolism as occurs for organic antimicrobial pesticides. In organisms and the environment, it is expected to slowly undergo dissolution to form zinc cations and undissociated boric acid. And the relevant species will be identified above in the proposed dissolution testing. We do not expect to conduct this study as it is not relevant for inorganic compounds.

Agency's Response: The Agency concurs with U.S. Borax, Inc's response and additional ready biodegradability study is not needed.

4. U.S. Borax's Comment:

Leachability of Wood Preservative (AWPA E11-06)

- U.S. Borax will provide data for the leachability of zinc borate for wood preservation uses. However, the suggested protocol AWP A E11-06 is designed for evaluating wood preservatives that are intended to treat material for ground contact uses. None of the wood composite materials treated with zinc borate are used in ground contact applications and therefore it is not appropriate to utilize ground contact evaluation procedures. Apart from WPC applications, all of the treated wood composite uses can be captured in one of two 'protected' use scenarios. The first is designated as AWP A Use Category 1 & 2 where they are intended for protected uses because of either interior application with no potential for human contact including flooring and sheathing or uses where they will be covered by building material like roofing. The other wood composite usage is for exterior above-ground applications that are protected with a three coat paint system such as exterior siding - this is AWP A Use Category 3A. With regard to WPCs, these are used as decking in unprotected above-ground application which is designated as AWP A Use Category 3B.
- Information currently exists from several studies including an accelerated leach test (ASTM C 1308) with wood plastic composites (WPCs) that provides an accelerated testing procedure for assessing the leach rate@). These studies show that the relatively water insoluble zinc borate has a very low leach rate from materials such as WPCs. The data also suggest

ROYCE ASSOCIATES
A LIMITED PARTNERSHIP

35 CARLTON AVENUE
EAST RUTHERFORD, N.J. 07073
TELEPHONE (201) 438-5200
FAX (201) 438-5207

April 12, 2012

Dr. Craig Bernard
U.S. Borax Inc.
8051 E. Maplewood Avenue, Bldg-4
Greenwood Village, CO 80111

Re: EPA DCI for Zinc Borate

Dear Dr. Bernard,

With regard to the recent EPA Generic Data Call-in Notice for Zinc Borate, and in confirmation of our earlier e-mail on March 5, 2012, Royce Associates ALP would like to formally notify you of our preference to enter into a cost-share agreement with all parties concerned in support of the generation of the new data being requested by EPA. Kindly advise if U.S. Borax would be willing to enter into such an agreement.

Please do not hesitate to call me at 973-279-0400 if you should have any questions.

Sincerely,



Philip L. Flor
EHS Mgr.

Via certified mail: 7011 0470 0002 3903 8522

cc: A.J. Royce IV